510(k) Summary
Dri-STAT® Enzymatic Bilirubin Reagent

1.0 **Submitted By:**

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Beckman Coulter, Inc.
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2.0 **Date Submitted:**

November 1, 2005

3.0 **Device Name(s):**

3.1 **Proprietary Names**
Dri-STAT® Enzymatic Bilirubin Reagent
SYNCHRON® Systems Bilirubin Calibrator

3.2 **Classification Name**
Bilirubin (total or direct) test system (21 CFR § 862.1110)
Calibrator (21 CFR § 862.1150)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
Dri-STAT® Enzymatic Bilirubin Reagent	Dri-STAT® Enzymatic Bilirubin Reagent	Beckman Coulter, Inc.*	K843174
SYNCHRON® Systems Bilirubin Calibrator	SYNCHRON® Systems Bilirubin Calibrator	Beckman Coulter, Inc.*	K791141

*Beckman Coulter, Inc., Brea, CA

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5.0 Description:

The Dri-STAT® Enzymatic Bilirubin Reagent Enzymatic Bilirubin may be used on the family of Synchron Systems in conjunction with the SYNCHRON® Systems Bilirubin Calibrator. The reagent kit contains two reagent bottles that needs to be manually transferred into a Beckman Coulter User-Define Cartridge

6.0 Intended Use:

Dri-STAT® Enzymatic Bilirubin Reagent, in conjunction with the SYNCHRON® Systems Bilirubin Calibrator, is intended for use in the in vitro diagnostic determination of total bilirubin in human serum and plasma as a User Defined Reagent (UDR) application on SYNCHRON® Systems.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

	Similarities	
TBE Reagent	Intended Use	Same as Beckman Coulter Dri-STAT® Enzymatic Bilirubin Reagent, Enzymatic Bilirubin on Cobas Fara
	Methodology	
	Reactive Ingredients	
	Sample Types	
	Shelf Life	
	Reaction Type	
	Calibrator	
	Differences	
	Instrument Platforms	SYNCHRON® Systems Vs Cobas Fara
	Analytical Range	Up through 35 mg/dL on predicate 0.2 – 25 mg/dL on candidate
	Reference Intervals	0.1-1.0 mg/dL on predicate 0.3-1.2 mg/dL per literature
	Wavelength	465 nm on predicate 470 and 520 nm on candidate
	Reaction Volumes	0.05; 1.00; 0.08 mL on predicate 10; 200; 16 µL on candidate

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8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, linearity, and imprecision experiments.

Dri-STAT Enzymatic Bilirubin Method Comparison Study Results

Candidate Method	Sample Type	Slope	Inter-cept	R	n	Predicate Method
Dri-STAT TBE Reagent On Synchron LX System	Serum	1.031	0.016	0.9997	70	Beckman Coulter Dri-STAT Enzymatic Bilirubin on Cobas Fara
Dri-STAT TBE Reagent On Synchron CX System	Serum	1.004	0.004	0.9997	70	Beckman Coulter Dri-STAT Enzymatic Bilirubin on Cobas Fara

Dri-STAT Enzymatic Bilirubin Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Serum Control 1	0.7	0.03	4.8	80
Serum Control 2	4.0	0.05	1.1	80
Serum Control 3	7.3	0.08	1.1	80
Human Pool	19.7	0.12	0.6	80
Total Imprecision				
Serum Control 1	0.7	0.03	4.8	80
Serum Control 2	4.0	0.06	1.4	80
Serum Control 3	7.3	0.11	1.5	80
Human Pool	19.7	0.47	2.4	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

SSE3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 2005

Ms. Eri Hirumi
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd.
Brea, CA 92822

Re: k053090
Trade/Device Name: Dri- STAT® Enzymatic Bilirubin Reagent
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: JFM
Dated: November 1, 2005
Received: November 2, 2005

Dear Ms. Hirumi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053090

Device Name: Dri-STAT® Enzymatic Bilirubin Reagent

Indications For Use:

Dri-STAT® Enzymatic Bilirubin Reagent, in conjunction with the SYNCHRON® Systems Bilirubin Calibrator, is intended for use in the in vitro diagnostic determination of total bilirubin in human serum and plasma as a User Defined Reagent (UDR) application on SYNCHRON® Systems.

Measurements of total bilirubin in serum and plasma are used in the diagnosis of hemolytic disorder, biliary obstruction, hepatitis and cirrhosis

Prescription Use __X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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